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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/618,852	07/15/2003	Lincoln Muir	IVGN 334	4340

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EXAMINER	
NEGIN, RUSSELL SCOTT	
ART UNIT	PAPER NUMBER
1631	

MAIL DATE	DELIVERY MODE
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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/618,852	MUIR ET AL.	
	Examiner	Art Unit	
	RUSSELL S. NEGIN	1631	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *11 June 2009*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *47-59* is/are pending in the application.

4a) Of the above claim(s) *55,57 and 58* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *47-54,56 and 59* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *14 June 2004* is/are: a)☒ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Election/Restrictions

Applicant's election without traverse of the C-terminal tag and the amber stop codon in the reply filed on 11 June 2009 is acknowledged. Histidine tags (claim 54) are also found in the prior art, and due to lack of search burden, are rejoined with the elected groups.

Claims 55 and 57-58 are withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to a nonelected species, there being no allowable generic or linking claim. Election was made **without** traverse in the reply filed on 11 June 2009.

Claims 47-59 are pending and claims 47-54, 56, and 59 are examined in the instant Office action.

Withdrawn Rejections

ALL of the rejections of the previous Office action are withdrawn in view of amendments filed to the instant claims on 11 June 2009.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

The following rejection is newly applied and necessitated by amendment:

Claims 47, 56, and 59 are rejected under 35 U.S.C. 102(b) as being anticipated by Temple et al. [Nature, volume 296, 1992, pages 537-540] in light of "Thalassemia: Treatments and Drugs;" obtained online on 21 August 2009.

Claim 47 is drawn to a clone collection comprising a plurality of clones wherein each clone contains an open reading frame that encodes a polypeptide of interest, wherein the polypeptide of interest is a druggable target, and wherein the open reading frame further comprises an internal suppressible stop codon.

The article of Temple et al. teaches construction of a functional human suppressor tRNA gene as an approach for gene therapy for beta-thalassaemia. Specifically, the abstract states that a human tRNA gene was converted to an amber (stop codon) suppressor by site directed mutagenesis; this mutant tRNA directed synthesis of other tRNA that suppressed the amber stop codon in beta-thalassaemia mRNA. Figure 3 on page 538 of Temple et al. illustrates the clone collection used to synthesize the desired RNA. The final paragraph on page 538 of Temple et al. teaches that this amber stop codon is internal and part of a reading frame of the RNA that translates into the beta-thalassaemia because the biomolecule length is affected by the stop codon suppression.

Although Temple et al. does not demonstrate that beta-thalassaemia is a druggable target, it is inherent from the Mayo Clinic article on "Thalassemia: Treatments and Drugs" that drugs are used to treat this protein related-illness.

With regard to claim 56, the suppressible stop codon described in the abstract of Temple et al. is the amber stop codon.

With regard to claim 59, as explained in the rejection of claim 47, the final paragraph on page 538 of Temple et al. teaches that this amber stop codon is internal and part of a reading frame of the RNA that translates into the beta-thalassaemia because the biomolecule length is affected by the stop codon suppression.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

The following rejection is newly applied and necessitated by amendment:

35 U.S.C. 103 Rejection #1:

Claims 48-50 and 54 are rejected under 35 U.S.C. 103(a) as being unpatentable over Temple et al. as evidenced by "Thalassemia: Treatments and Drugs" as applied to claims 47, 56, and 59 above, in further view of Janknecht et al. [PNAS, 1991, volume 88, pages 8972-8976].

Claim 48 is further limiting wherein the protein of interest is a fusion protein.

Claim 49 is further limiting wherein the nucleic acid encoding the fusion protein has at least two suppressible stop codons.

Claim 50 is further limiting wherein the fusion protein contains an affinity tag.

Claim 54 is further limiting wherein the affinity tag is a histidine tag.

Temple et al. teaches the clone collection with suppressible stop codons as discussed above. Furthermore, Temple et al. suggests in the penultimate paragraph of the article on page 540 that the method could be used for other amber stop codons besides the stop codon mentioned in the anticipatory prior art rejection above.

Temple et al., however, does not teach that the protein of interest is a fusion protein, or that the fusion protein has an affinity tag such as histidine.

The article of Janknecht et al. studies rapid and efficient purification of histidine tagged protein expressed by recombinant vaccinia virus. Specifically, Figure 1 of Janknecht et al. illustrates the DNA and protein deduced sequence of the amino terminus of the SRF-6His fusion protein.

It would have been obvious to someone of ordinary skill in the art at the time of the instant invention to modify the suppressible stop codon and protein expression study of Temple et al. by use of expression of histidine tagged fusion proteins of Janknecht et al. wherein the motivation would have been that tagging the fusion proteins with an agent such as histidine allows more rapid and efficient purification [see title on page 8972 of Janknecht et al.] It would have been further obvious to use a fusion protein as in Janknecht et al. as opposed to a "native" protein as in Temple et al. because it is obvious to substitute known elements in the prior art to yield a predictable result. In this instance, the fusion protein is an alternate form of protein than the "native" protein. There would have been a reasonable expectation for success in combining Temple et al. and Janknecht et al. because both are analogous studies of protein expression.

The following rejection is newly applied and necessitated by amendment:

35 U.S.C. 103 Rejection #2:

Claims 51-53 are rejected under 35 U.S.C. 103(a) as being unpatentable over Temple et al. as evidenced by "Thalassemia: Treatments and Drugs" in view of Janknecht et al. as applied to claims 47-50, 54, 56, and 59 above, in further view of Muller et al. [Analytical Biochemistry, 1998, volume 259, pages 54-61].

Claim 51 is further limiting wherein the affinity tag is a C-terminal tag.

Claim 52 is further limiting wherein a suppressible stop codon is located immediately after the nucleic acid region that encodes the C-terminal tag.

Claim 53 is further limiting wherein a suppressible stop codon is within the open reading frame encoding the polypeptide of interest.

Temple et al. and Janknecht et al. make obvious the clone collection with suppressible stop codons that are located in the open reading frame of the polypeptide of interest, as discussed above.

Temple et al. and Janknecht et al. do not teach that the affinity tag is a C-terminal tag or the proximity of this tag to the stop codon.

The article of Muller et al. studies the purification of His-tagged proteins.

Specifically, the Proteins section of Materials and Methods describes the synthesis and purification of both C-terminal and N-terminal His-tagged proteins. As the last expressed amino acid was the final histidine of the tag, the stop codon is proximal to this codon encoding histidine.

It would have been obvious to someone of ordinary skill in the art at the time of the instant invention to modify the suppressible stop codon and protein expression study of Temple et al. and the use of expression of histidine tagged fusion proteins of Janknecht et al. by use of specific C-terminal His-tagging of Muller et al. wherein the motivation would have been that during purification and binding, sometimes only proteins with C-terminal tags are recognized [see column 1 on page 58 of Muller et al.]

Conclusion

No claim is allowed.

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Papers related to this application may be submitted to Technical Center 1600 by facsimile transmission. Papers should be faxed to Technical Center 1600 via the central PTO Fax Center. The faxing of such pages must conform with the notices published in the Official Gazette, 1096 OG 30 (November 15, 1988), 1156 OG 61 (November 16, 1993), and 1157 OG 94 (December 28, 1993)(See 37 CFR § 1.6(d)). The Central PTO Fax Center Number is (571) 273-8300.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Russell Negin, whose telephone number is (571) 272-1083. The examiner can normally be reached on Monday-Friday from 7am to 4pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's Supervisor, Marjorie Moran, Supervisory Patent Examiner, can be reached at (571) 272-0720.

Information regarding the status of the application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information on the PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

/RSN/
Russell S. Negin
21 August 2009

/Marjorie Moran/
Supervisory Patent Examiner, Art Unit 1631